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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,969	09/11/2003	Wael R. Joseph	19378B (27839-725)	5031
45736 7590 12/11/2009 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
12/11/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary

Application No.

10/659,969

Applicant(s)

JOSEPH ET AL.

Examiner

HASAN S. AHMED

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 12-17, 20-33, 35-40, 42, 44-47, 50-64 and 66-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-17, 20-33, 35-40, 42, 44-47, 50-64, and 66-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks filed on 19 August 2009.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-8, 10, 12-17, 20-22, 25-30, 32, 33, 35-40, 42, 44-47, 50-55, 58-60, 62-64, 66, 68 and 70-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") (cited in the IDS of 18 October 2004) in view of U.S. Patent No. 6,570,054 ("Gatto") (cited in the IDS of 31 October 2003) further in view of US 20030157195 ("Bartels") (cited in the IDS of 16 September 2008).

Krzysik teaches an absorbent product (see page 3, line 78). The absorbent product disclosed is comprised of:

- the moisturizing and lubricating compositions of instant claims 1, 32, and 62 (see page 3, lines 93-103);
- the emollient (dimethicone) of instant claims 1 and 62 (see page 19, formula 6);
- the humectant (glycerin) of instant claims 1, 32, and 62 (see page 5, line 150);
- the immobilizing agent (PEG 8000) of instant claims 1, 32, and 62 (see page 5, line 156);

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- the compatibilizing agent (propylene glycol) of instant claims 1, 32, and 62 (*see* page 5, lines 149-150);
- the silicone (dimethicone) of instant claim 2 (*see* page 19, formula 6);
- the dimethicone of instant claims 3 and 35 (*see* page 19, formula 6);
- the glycerin of instant claims 5-7 and 37-39 (*see* page 5, line 150);
- the PEG 8000 of instant claims 1,10, 42, and 62 (*see* page 5, line 156);
- the propylene glycol of instant claims 12 and 44 (*see* page 5, lines 149-150);
- the dispersing agent (DC 1428) of instant claims 13 and 63 (*see* page 19, formula 6);
- the modified polydimethylsiloxane (DC 1428) of instant claim 14 (*see* page 19, formula 6);
- the skin barrier enhancing agent (natural fats or oils) of instant claims 16, 46, and 64 (*see* page 3, line 100);
- the avocado oil of instant claims 17 and 47 (*see* page 7, line 215);
- the sterol derivative of instant claims 21 and 66 (*see* page 3, line 99);
- the cholesterol of instant claims 21, 22, 51, and 52 (*see* page 5, line 160);
- the surfactant of instant claims 25, 53, and 68 (*see* page 3, line 98); and
- the sorbitol of instant claim 70 (*see* page 5, line 158).

Krzysik explains that the disclosed absorbent product is beneficial because it improves skin health by enhancement of skin barrier function (*see* page 1, lines 7-8).

Krzysik does not teach the particular antioxidants listed in claims 20 and 50. Gatto teaches an absorbent article with a skin care composition (*see* abstract). The

skin care composition may contain BHT (see col. 25, line 1). Gatto does not disclose the concentration of BHT, however, Bartels teaches a skin care composition wherein the BHT concentration is 0.001-10% (see Example 1), overlapping with the concentration instantly claimed.

Krzysik does not explicitly teach all the percentages recited in instant claims 1, 4, 8, 15, 18, 21, 26, 27, 32, 36, 40, 45, 48, 51, 54, 55, and 71-74 (or the ratio recited in instant claim 33), however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art. Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges. The Krzysik reference teaches ranges that overlap with the instant claims regarding: (a) emollient (10% - see page 19, formula 6); (b) humectant (hydrophilic solvent, i.e., glycerin (see page 5, line 150)) (10-95% - see page 3, line 94); (c) immobilizing agent (high MW PEG) (5-95% - see page 3, lines 94-95); (d) compatibilizing agent (hydrophilic solvent, i.e., propylene glycol (see page 5, lines 149-150)) (10-95% - see page 3, line 94); (e) skin barrier enhancing agent (natural fats or oils) (0.1 - 30% - see page 3, line

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100); (f) antioxidant (tocopherol) (0.3% - see page 18, formula 1); (g) melting point (30 degrees C - 100 degrees C – page 5, line 141); and (h) penetration hardness (5 millimeters - 360 millimeters – page 5, line 142-143).

The Krzysik reference is silent with respect to the (1) phase temperatures of instant claims 1, 28-30, 32, 58-60, and 62; and (2) solubility/dispersibility in deionized water of instant claims 1, 32, 62, and 70. As claimed, applicants' article is the same as the prior art. As claimed, it contains the same components in the same configuration and overlapping amounts. Properties are the same when the structure and composition are the same. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product, as taught by Krzysik. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they improve skin health by enhancement of skin barrier function, as explained by Krzysik (see above)

*

2. Claims 1, 23, 24, 32, 56, 57, 62, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") in view of U.S. Patent No. 6,570,054 ("Gatto") (cited in the IDS of 31 October 2003) further in view of US 20030157195 ("Bartels") (cited in the IDS of 16 September 2008) in view of US 5,342,976 ("Bowser").

Krzsik, Gatto, and Bartels are discussed above.

The Krzsik reference differs from the instant application in that it does not teach the ceramide of claims 23, 56, and 67 or the glucosylceramide of instant claims 24 and 57.

Bowser teaches a skin composition that may be used in an absorbent product, such as a tissue wipe (*see* col. 16, line 44).

The disclosed composition contains the ceramide glucosylceramide (*see* col. 1, line 67).

Bowser explains that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." *See* col. 2, lines 7-9.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add glucosylceramide to an absorbent product, as taught by Krzsik in view of Bowser. One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser.

*

3. Claims 1, 31, 61, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64409 ("Krzysik") in view of U.S. Patent No. 6,570,054 ("Gatto") (cited in the IDS of 31 October 2003) further in view of US 20030157195 ("Bartels") (cited in the IDS of 16 September 2008) in view of US 6,153,209 ("Vega").

Krzysik, Gatto, and Bartels are discussed above. Krzysik differs from the instant application in that it does not teach the particular absorbent products listed in claims 31, 61, and 69.

Vega teaches an absorbent product (see col. 1, line 7) comprising a moisturizing and lubricating composition (see col. 25, line 65 - col. 26, line 14) which in turn is comprised of an emollient (see col. 15, line 26), a humectant (see col. 25, line 65 - col. 26, line 14), an immobilizing agent (e.g. PEG-30 and PEG-50, see col. 26, line 6), and a compatibilizing agent (e.g. propylene glycol, see col. 26, lines 5-11). The absorbent product disclosed by Vega is, *inter alia*, a diaper (see col. 1, line 7).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product such as a diaper, as taught by Krzysik in view of Vega. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they improve skin health by enhancement of skin barrier function, as explained by Krzysik (see above)

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 12-33, 35-40, 42, and 44-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because '862 claims a tissue product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. See claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed 19 August 2009 have been fully considered but they are not persuasive.

Applicants argue that the prior art references do not disclose the specific antioxidants at the specific concentrations being claimed with the latest amendment.

Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As discussed in the modified 35 USC 103 rejection above, the Gatto reference discloses BHA, one of the antioxidants currently claimed, and the Bartels reference discloses BHA in a concentration overlapping with that being claimed currently. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In *re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

* * * * *

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

